PSJ14 Janssen Opp Exh 31 – ODM 004316

ODJFS P&T Committee Meeting Minutes

October 7, 2009
77 S. High St., Room 1960

Committee members present: Susan Baker, APN; Ioanna Giatis, DO; Cheryl Huffman, MD; Robert L. Hunter, DO (chair); Margaret Scott, RPh; Mary Jo Welker, MD

ACS staff present: Stephanie Levine, PharmD, Clinical Manager

Approximately 25 stakeholders were present, most representing pharmaceutical manufacturers.

The meeting was called to order at 10:10 AM.

1. Changes to Ohio Revised Code section 5111.084 regarding the P&T Committee. The statutory language is attached. The changes passed in Amended Substitute House Bill 1, the Ohio budget bill, place several requirements on the committee. Some of these, such as timeframes for posting the agenda and minutes on the website, will be handled by ODJFS staff. Others affect the Committee members directly. First, the committee will be required to vote, and a majority of the quorum is needed to make a recommendation. In the past, recommendations have been made by consensus. Second, the Committee must permit interested parties to make a presentation or submit written material to the Committee.

The Committee discussed how the interested party presentations should be handled. Discussion about a time limit for the speakers ranged from 10 minutes per speaker to 10 minutes divided between all speakers. The Committee decided on a maximum of 5 minutes per speaker, with the opportunity to limit the time if there are a large number of speakers. Members would like interested parties to submit written materials in advance, so requests may be screened. The Committee must allow the interested party to either speak or provide written comments, so members will decide based on the request and written information whether the interested party will be allowed to speak or to submit written materials. The topics should be limited to those on the meeting agenda. Interested parties should also disclose any conflict of interest. The request to present information should be made after the agenda is posted to the ODJFS website. The agenda must be posted 14 days in advance of the meeting, so requests from interested parties must be made by close of business on the Friday after the agenda is posted. Interested party presentations will be included on the meeting agenda before any drugs under consideration. Ms. Scott will write guidelines and share them with the ODJFS Office of Legal Services to be sure they meet the statutory requirements. The Committee will review and approve the guidelines at the next meeting in January.

2. Drugs under consideration
   a. Platelet Aggregation Inhibitor: Effient (prasugel) tablets, Lilly
      Lilly has asked to defer their presentation until the next meeting. Effient will continue to require prior authorization until it has been reviewed.
   b. Analgesics: Nucynta (tapentadol) tablets CII, Ortho-McNeil-Janssen
      The manufacturer made a clinical presentation. Dr. Welker asked about the relative cost of Nucynta vs. available opioids. The manufacturer responded that the AWP price per tablet is roughly $1.70 while available generic alternatives such as oxycodone are pennies per dose. Dr. Welker also asked about addiction potential, because the drug is a CII and according to the clinical presentation has fewer side effects than traditional opioids. The

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manufacturer's representative said that there is potential for addiction, but Nucynta has less opioid activity than traditional opioids. Dr. Hunter said that the FDA's recent attention to acetaminophen and the possibility of acetaminophen combinations no longer being available may make Nucynta a good alternative, and that perhaps the prior authorization criteria for Nucynta should require a trial on only one preferred opioid product. Dr. Huffman said that acetaminophen is usually only a problem with patients who take the products inappropriately. Dr. Welker said that the prescriber can always increase the oxycodone dose if there is a concern about acetaminophen. Ms. Baker said Nucynta may be a good alternative if the acetaminophen combinations are pulled from the market. Ms. Scott noted that the cost per day of therapy for Nucynta is about $10 while the cost per day of therapy of alternative generic products is about $2 per day. Dr. Levine presented the recommendation from ACS and ODJFS that Nucynta be non-preferred. Dr. Hunter called for a vote. All members voted that Nucynta should be non-preferred, requiring prior authorization according to established preferred drug list (PDL) criteria.

c. Oral Hypoglycemics: Onglyza (saxagliptin) tablets, Bristol-Myers Squibb
The manufacturer made a clinical presentation. Dr. Welker asked about the relative cost of Onglyza compared to Januvia. The manufacturer's representative said that at the AWP level it is priced about the same. Ms. Scott read from e-mails sent by Michael Wascovich, RPh, and Suzanne Eastman, RPh, members of the committee who were unable to attend the meeting, that they recommended prior authorization because of the potential for drug interactions. Dr. Welker said she saw no reason for prior authorization. Dr. Levine presented the recommendation from ACS and ODJFS that Onglyza be preferred. Dr. Hunter called for a vote. All members voted that Onglyza should be preferred, available without prior authorization.

3. Follow-up on questions raised at July 2009 Committee meeting: Twice-daily (BID) dosing of proton pump inhibitors (PPIs) and changes in utilization of hematopoietic agents following label changes.
Dr. Levine presented claims data showing that only 6% of PPI users are receiving BID dosing. Based on this low percentage, no changes are recommended at this time. Dr. Welker noted that about 1/3 of consumers received a prescription for a PPI. Ms. Scott said that the Drug Utilization Review (DUR) Board is looking at PPI utilization. The first thing that the DUR program is reviewing is continuous use of the same drug, same dose, for a long period. 238 patients have been identified who received 18 months' worth of doses in an 18-month time period. The DUR Board is also concerned about as-needed (PRN) use, since this is not an appropriate use of PPIs. Since such a large number of patients have received PPIs, and a low number are using them continuously, PRN dosing is likely a bigger problem.
Dr. Levine also presented information showing that the number of claims and amount spent on the hematopoietic drugs Aranesp, Procrit, and Epogen has remained steady for several years, indicating that the labeling changes have not significantly affected utilization in the Medicaid population.

4. Interested party presentations
No interested parties wished to make a presentation.

5. Announcements

Ms. Scott discussed ODJFS' plans to carve pharmacy out of the managed care benefit. Beginning February 1, 2010, all Ohio Medicaid consumers will move to the fee-for-service pharmacy program, meaning that there will be one list of covered drugs and one prior authorization policy for all 1.7 million consumers. ODJFS and the managed care plans are working closely to make sure everything goes smoothly. ODJFS will have claims history from the managed care plans so an adequate transition plan can be in place before members must use the fee-for-service PDL. Details have not been finalized. The workgroups are deciding whether prior authorizations given by the managed care plans also need to be transferred. Since the managed care plans have many more drugs on prior authorization the fee-for-service, this may not be the best strategy. Selected prior authorizations, including those for Synagis, will be transferred.

ODJFS is also proposing to end coverage of selected over-the-counter drugs for adults age 21 and over. This proposed change is under review with no implementation date.

The next meeting is scheduled for Wednesday, January 27, 2010, at 10 AM in the same room.

The meeting was adjourned at 11:08 AM by Dr. Hunter.

Following the meeting, ODJFS followed the Committee's recommendations to make Nucynta® non-preferred and Onglyza® preferred. Onglyza® was available without prior authorization beginning October 10.